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OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed 1.2mm Auto-Drive Screw System
Device Common Name:	Small Bone Screw
Classification Name:	Screw, Fixation, Bone
Name of Submitter:	OsteoMed Corporation 3750 Realty Road Addison, Texas 75001 Phone: (972) 241-3401 Fax: (972) 241-3507
Contact Person:	Dawn T. Holdeman
Date Prepared:	September 16, 2002

Summary:

This submission describes the OsteoMed 1.2mm Auto-Drive Screw System indicated for fixation secondary to trauma or reconstruction of the craniofacial and maxillofacial skeleton and bones of the hand. 1.2 mm Auto-Drive Screws are intended for single patient use only.

The OsteoMed 1.2mm Auto-Drive Screw System is comprised of 1.2mm diameter screws in lengths ranging from 3.0mm to 6.0mm. System instruments include screwdrivers and driver bits.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the OsteoMed Auto-Drive Bone Screw (K974785), the Synthes 1.3mm Self-Drilling Screw (K983485), and the Leibinger Self-Drilling Screw (K970912).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed 1.2mm Auto-Drive Screw System does not raise any new safety or effectiveness issues.

3750 Realty Road
Addison, Texas 75001-4311
(972) 241-3401 FAX: (972) 241-3507
Customer Service: (800) 456-7779

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Osteomed Corporation
Dawn T. Holdeman
Regulatory Affairs and Document Control
3750 Realty Road
Addison, Texas 75001-4311

Re: K023260
Trade/Device Name: OsteoMed 1.2mm Auto-Drive Screw System
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 27, 2002
Received: September 30, 2002

Dear Ms. Holdeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023260
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OsteoMed "Indications for Use" Submission

510(k) Number: K023260

Device Name:	OsteoMed 1.2mm Auto-Drive Screw
Indication for Use:	Indicated for fixation secondary to trauma or reconstruction of the craniofacial and maxillofacial skeleton and bones of the hand. 1.2mm Auto-Drive Screws are intended for single patient use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 810.109)

Over-The Counter-Use _____
(Optical Format 1-)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023260